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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,888	06/14/2001	Joseph P. Steiner	23138A-T	7207

29728 7590 02/17/2004

GUILFORD PHARMACEUTICALS C/O  
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WASHINGTON, DC 20007-5143

EXAMINER
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COOK, REBECCA

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 02/17/2004

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/879,888

Applicant(s)

STEINER ET AL.

Examiner

Rebecca Cook

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 17-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The final rejection has been withdrawn and prosecution is reopened in view of the rejections that follow.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 33 is rejected under 35 U.S.C. 102(b) as being anticipated by 5,801,187 for the reason given in Paper No. 8 of 3/8/02 and affirmed by the BPAI on 9/25/03.

#### ***Claim Rejections - 35 USC § 112***

Claims 17-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 recites the phrase “an effective”. The claims further recite “a second compound for treating alopecia or promoting hair growth.” However, it is not clear if an effective amount of a compound for treating alopecia or promoting hair is required and if the second compound is provided in an effective amount. Furthermore, there is no antecedent basis in the claim for the recitation “a compound for treating alopecia or promoting hair growth.”

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5, 6, 8 of copending Application No. 09/784,174. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Instant claim 17 recites

"A pharmaceutical composition which comprises:

- (i) an effective amount of a nitrogen-containing heterocyclic compound having two or more heteroatoms, wherein said compound has a substituents -C(W)-C(Y)- which is attached to a nitrogen atom of the heterocyclic ring, wherein W and Y are independently selected from the group consisting of O, S, CH<sub>2</sub>, and H<sub>2</sub>, and wherein said compound is additionally substituted with a ester or amide substituents attached to any atom of the heterocyclic ring other than said nitrogen atom provided that said ester or amide substituents is not an N-oxide of an ester or amide and further provided that said amide substituents is linked to the heterocyclic ring with a carbon-carbon bond,
- (ii) a second compound for treating alopecia or promoting hair growth; and
- (iii) a pharmaceutically acceptable carrier."

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In Application Serial No. 09/784,174 Instant claim 5 recites

“A pharmaceutical composition which comprises:

(i) an effective amount of a compound for treating alopecia or promoting hair growth in an animal in need thereof, wherein said compound is of formula I...

(ii) a second hair revitalizing agent; and

(iii) a pharmaceutically acceptable carrier.”

In claim 5 the compound of formula I is an N linked ketone or diketone, when M is O. The compound is either an ester or amide, depending on whether A is O, NH or N-(C<sub>1</sub> –C<sub>4</sub>) alkyl. The compound is acyclic or has a 7-membered heterocyclic ring when J and K are taken together. Said ring is further substituted with O, S, SO or SO<sub>2</sub>.

Instant claim 6 recites

“A pharmaceutical composition which comprises:

(i) an effective amount of a compound for treating alopecia or promoting hair growth in an animal in need thereof, wherein said compound is of formula II...

(ii) a second hair revitalizing agent; and

(iii) a pharmaceutically acceptable carrier.”

In claim 6 the compound of formula II is an N linked ketone or diketone when E is O. The compound is either an ester or amide, depending on whether A is O, NH or N-(C<sub>1</sub> –C<sub>4</sub>) alkyl. The compound is acyclic or has a 7-membered heterocyclic ring when J and K are taken together. Said ring is further substituted with O, S, SO or SO<sub>2</sub>.

Instant claim 8 recites

“A pharmaceutical composition which comprises:

(i) an effective amount of a compound for treating alopecia or promoting hair growth in an animal in need thereof, wherein said compound is of formula IV...

(ii) a second hair revitalizing agent; and

(iii) a pharmaceutically acceptable carrier.”

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In claim 8 the compound of formula II is an N linked ketone or diketone when E is O and V is N. The compound is either an ester or amide, depending on whether A is O, NH or N-(C<sub>1</sub> –C<sub>4</sub>) alkyl. The compound is acyclic or has a 7-membered heterocyclic ring when J and K are taken together. Said ring is further substituted with O, S, SO or SO<sub>2</sub>.

The instant claims would be obvious to one of ordinary skill in the art in view of '174, since both applications recite a composition comprising (i) a first compound which can be an N-linked ketone or diketone, when instant W and Y are O and in '174 E is O; both compounds can be an ester or amide, depending on whether in '174 A is O or NH, both compounds have a 7-membered heterocyclic ring when instant J and K are taken together and the instant application has two or more heteroatoms when the ring is further substituted with O, S, SO or SO<sub>2</sub>.

Furthermore, the instant application recites (ii) a second compound for treating alopecia or promoting hair growth and '174 recites "a second compound for revitalizing hair." It would be obvious to one of ordinary skill in the art that the intent of the phrases "treating alopecia or promoting hair growth" and "revitalizing hair" are the same, since in '774 the second compound is paired with a first compound having the intent to treat alopecia.


This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571)272-0571.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (571)272-0584.

  
REBECCA COOK  
PRIMARY EXAMINER  
GROUP 4200/614

February 11, 2004